JUL 17 2009

K090587

510(k) Summary

I. Applicant Information

- Applicant's Name and Address: Orthomerica Products Inc, 505 31st Street, P.O. Box 2927, Newport Beach, CA 92659, Telephone: (949) 723-4500, Facsimile: (949) 723-4501

  FDA Establishment Registration Number 1058152

- Contact: David C. Kerr, Chief Executive Officer, Telephone: (949) 723-4500, Facsimile: (949) 723-4501

- Submission Correspondent: Alan T. Sandifer, Director of Research and Development, 6333 North Orange Blossom Trail, Orlando, FL 32810, Telephone: (407) 290-6592, Facsimile: (407) 290-1303, asandifer@orthomerica.com

- Summary Date – June 9, 2009

II. Submission Information

- Type: 510(k) Device Modification (Special)
- Proprietary Name: STARlight
- Common Name: Cranial Orthosis
- Classification: Class II (special controls); OAN; MVA; 21 CFR 882.5970
- Classification Name: Cranial Orthosis
- Predicate Device: STARlight, Cranial Orthosis, K082945

III. Manufacturing Site: 6333 North Orange Blossom Trail, Orlando, FL 32810, Telephone: (407) 290-6592, Facsimile: (407) 290-2419, FDA Establishment Registration Number 1058152

IV. Description of Device

The STARlight redirects the head growth to improve proportion and symmetry. The practitioner takes a plaster impression or scan of the baby's head to acquire the existing shape. The mold is sealed and filled with plaster or the scanned shape is carved from a rigid polyurethane foam blank to create a positive model of the head shape. The positive model is modified to obtain greater symmetry and space in the areas of flattening. The STARlight provides total contact over the prominent or bossed areas of the baby's head to discourage growth there. Over the course of treatment, the inside of the band is modified further by the practitioner to provide space for growth to occur in the flat or depressed areas. The shape of the STARlight directs growth into the areas of least resistance and creates a precise pathway for the head shape to improve in symmetry and proportion.

The proposed modification is the addition of the STARlight PRO design, which is an amalgamation of the STARlight Side Opening design and the STARlight Cap design.

The STARlight Side Opening design, STARlight Bi-Valve design and the STARlight Cap design are all made of a plastic shell of 5/32" – 1/4" clear Surlyn or 1/8" - 7/32" Clear Co-Polyester. The STARlight PRO (Post-operative Remolding Orthosis) design uses a 1/4" to 3/8" clear Surlyn shell for patients with a head circumference over 18" (over approximately 1 year of age) and a 5/32" to 1/4" clear Surlyn shell for all patients with a head circumference less than 18". The STARband Bi-Valve design is made with an outer shell of 5/32" polyethylene-polypropylene copolymer plastic and an inner liner of 1/2" pelite polyethylene foam. Optional Aliplast (closed cell polyethylene) padding is available for the clear plastic bands and in addition optional Reston (polyurethane – 3M Medical Product) foam is available for the STARlight PRO design.

The STARlight Cap design is made of the above plastic and contains no straps. The STARlight Side Opening design has a top opening and a side opening. The band is held in place by a Velcro strap across the side opening. The STARlight PRO has two side openings, no top opening, and is held in place by a Velcro strap across each side opening. The STARlight Bivalve design and the STARband Bi-Valve design consist of two plastic shells that overlap with a superior sliding mechanism. The right and left overlap tabs are connected via a Velcro strap with chafe and loop.

V. Statement of Indications and Intended Use

Statement of Indications:

The STARlight is intended for medical purposes for use on infants from three to 18 months of age, with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. The device is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

Intended Use:

The intended use is the same as it was for the STARlight in K082945; to correct head shape and proportion deformities. The STARlight is available by prescription only and is designed to treat infants with abnormal head shapes from age 3 to 18 months. Since growth is the driving factor in head shape correction, the infants wear the STARlight for approximately 23 hours per day. The most common head deformities are positional plagiocephaly, brachycephaly, and scaphocephaly. Recently the STARlight has also been cleared to treat unresolved head deformities in patients who have undergone surgery to correct craniosynostosis. The same principles of cranial remolding apply to positional deformities and post-operative patients. Although the STARlight PRO was specifically designed for post-operative patients, the common operating principles also allow it to be used for deformational head shapes.

VI. Summary of Technological Characteristics

The modification proposed is a new STARlight design, the STARlight PRO. Although the material thickness has changed slightly, the underlying principles of operation of the STARlight PRO remain identical to the other STARlight designs.

Table 1 – Comparison of Predicate Device cleared in K082945 to proposed device

Feature	From K082945	Proposed Device
Indications	The STARlight is intended for medical purposes for use on infants from three to 18 months of age, with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. The device is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.	The STARlight is intended for medical purposes for use on infants from three to 18 months of age, with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. The device is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.
Mechanism	Applies pressure to the prominent regions of the infants cranium in order to improve cranial symmetry and/or shape	Applies pressure to the prominent regions of the infants cranium in order to improve cranial symmetry and/or shape
Materials	Material for STARlight Side Opening, STARlight Bi-Valve, STARlight Cap - 5/32" - 1/4" clear Surlyn or 1/8" – 7/32" Clear Co-Polyester plastic shell Material for STARband Bivalve - Outer shell of 5/32" copolymer plastic - An inner liner of 1/2" pelite polyethylene foam Closure for Bivalve design - Sliding/Overlap closure system - Chicago screw (or similar) for top sliding mechanism - 1" velcro strap - 1" chafe buckle - 91X speedy rivets Closure for Side Opening design: - 1" Velcro Strap	Material for STARlight Side Opening, STARlight Bi-Valve, STARlight Cap - 5/32" - 1/4" clear Surlyn or 1/8" – 7/32" Clear Co-Polyester plastic shell Material for STARlight PRO - 1/4" – 3/8" clear Surlyn for patient with a head circ ≥18" - 5/32" – 1/4" clear Surlyn for patient with a head circ ≤18" Material for STARband Bivalve - Outer shell of 5/32" copolymer plastic - An inner liner of 1/2" pelite polyethylene foam Closure for Bivalve design - Sliding/Overlap closure system - Chicago screw (or similar) for top sliding mechanism - 1" velcro strap - 1" chafe buckle - 91X speedy rivets Closure for Side Opening design and the PRO design: - 1" Velcro Strap (qty 2 for the PRO design)

Feature	From K082945	Proposed Device
Product Design	Custom made cranial orthosis, approx 7 to 10oz. in weight	Custom made cranial orthosis, approx 7 to 10oz. in weight, however, the new STARlight PRO weighs approx 7-12 oz for patients with a head circumference less than 18" and 12.5 to 18.5 oz for patients with a head circumference over 18".
Production	- Form orthosis from a positive mold of infant's head - Positive mold is formed based upon measurements of the infant's head taken by the STARscanner or the OWW Omega Scanner from which a 3-dimensional image is made or from a traditional plaster cast - The 3-dimensional image is used to produce a positive mold using a 5-axis routing machine	- Form orthosis from a positive mold of infant's head - Positive mold is formed based upon measurements of the infant's head taken by the STARscanner or the OWW Omega Scanner from which a 3-dimensional image is made or from a traditional plaster cast - The 3-dimensional image is used to produce a positive mold using a 5-axis routing machine

As the table illustrates, the only change in the device is a change in material thickness to increase the rigidity for the STARlight PRO for patients with a head circumference greater than 18" or approximately 1 year or older. Inherently this change also increases the weight.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Orthomerica Products, Inc.
c/o Alan T. Sandifer
Director of Research and Development
6333 N. Orange Blossom Trail, Ste. 220
Orlando, FL 32810

JUL 17 2009

Re: K090587
Trade/Device Name: STARlight Cranial Orthosis
Regulation Number: 21 CFR 882.5970
Regulation Name: Cranial Orthosis
Regulatory Class: II
Product Code: OAN
Dated: June 15, 2009
Received: June 17, 2009

Dear Mr. Sandifer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090587

Statement of Indications for Use

510K Number (if known): K090587

Device Name: STARlight®

Indications for Use:

The STARlight is intended for medical purposes for use on infants from three to 18 months of age, with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic- and scaphocephalic-shaped heads by applying mild pressure to prominent regions of the infant's cranium in order to improve cranial symmetry and/or shape. The device is also indicated for adjunctive use for infants from three to eighteen months of age whose synostosis has been surgically corrected, but who still have moderate to severe cranial deformities including plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jeffrey Toy

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K090587